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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Celal Albayrak

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KAGAN BINDER, PLLC

SUITE 200, MAPLE ISLAND BUILDING

221 MAIN STREET NORTH

STILLWATER, MN 55082

EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

10/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,952	Applicant(s) ALBAYRAK, CELAL	
	Examiner MAURY AUDET	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/15/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response is acknowledged.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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The rejection of claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchinson (US 5,889,110) in view of Chen et al. (US 7,081,489), Bhagwatwar et al. (US 20030049320) and Yeh et al. (US 5869103, cited by International Authority in related PCT Search Report), is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. Specifically, even after Chen et al. was cited, Applicant argues that the combination of references does not teach a method of carrying out the process in solution; and that the active substance is not precipitated in the polymer solution prior to solidifying the polymer. Applicant's arguments have been fully considered, but even if not expressly taught, as the Examiner has concluded, and in light of what the skilled artisan was well versed in, the aforementioned form/sequence of arriving at the same end product, absent a clear unexpected result, would have merely been a matter of routine optimization by one of ordinary skill in the art, to arrive at, absent more convincing evidence to the contrary.

The rejection is repeated below for continuity of record:

Applicant argues that the combination of references does not teach the precipitation of the active substance prior to solidification. Chen et al. is cited to remedy this deficiency, while falling within analogous art to Hutchinson and providing motivation to arrive at the claimed invention.

Hutchinson was discussed previously (see entire document). Due to the present claims amorphous language, it is still unclear whether the steps of Hutchinson, in various examples,

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expressly teach the "effecting precipitation" step as comprising an L 1/L2 combination wherein the latter is increased over the former (Applicant's claims 2-4). It is clear Hutchinson teach L1/L2, wherein the latter is increased, following a precipitation step, and wherein the L2 is a non-solvent to the goserelin acetate (see e.g. claim 16, step iv)). This seems to be the only issue, as to whether Hutchinson expressly teaches within one of the examples this stepwise approach, or whether such would have been merely obvious. Additionally, it is not clear whether Hutchinson teach volume fraction of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents combined in step (b) (Applicant's claim 7).

Chen et al. teach making of polymeric nanoparticles comprises providing active agent nanoparticles having average diameter of 5-100 nm. The active agent nanoparticles are treated with an anionic surfactant to form modified active agent nanoparticles. The modified nanoactive agent nanoparticles are mixed with a solution of polymer in a *solvent at first temperature*, which is greater than the melting temperature of the polymer and less than boiling point of the *solvent to form a first mixture*. The mixing comprises the use of sonication. *A non-solvent is mixed with first mixture to form a second mixture*. The second mixture is sonicated to form an emulsion. The emulsion is cooled to a *second temperature at a rate effective to precipitate polymeric nanoparticles* comprising the polymer with the modified active agent nanoparticles (abstract, entire document).

As previously discussed, Bhagwatwar et al teach a method of forming microparticles comprising the elected species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide (e.g. para 158, claims 8, 26, 37, and 47), with any suitable solution/solvent well known in the art (e.g. para 2-5, 40, 75, entire document), and contemplating any Well

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known microparticle size well known in the art for the use of microparticles in vivo.

Bhagwatwar et al. teach microparticles, but does not expressly teach that microparticles includes the species nanoparticles and specific size ranges under 1 um, was not expressly found therein (e.g. Applicant's claim 11).

As previously discussed, Yeh et al. teach the formation of nano/microparticle, which comprises active substances and the polymer poly-DL-lactide-co-glycolide, including in size ranges less than 1 um (e.g. col. 1, col. 3, lines 35-41, entire document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at an L1/L2 solvent mixture as part of the "effecting precipitation" step, in Hutchinson, because Chen et al. advantageously teach the that the active substance is not added in solid state to the polymer solution and is formed in situ and precipitated as part of the solvent process. Hutchinson, within the analogous art, advantageously teach various steps and means of carrying out the same ultimate goal of microparticle formation comprising active substance goserelin acetate within polymer poly-DL-lactide-co-glycolide, and further in view of the advantageous teachings of Chen et al., as well as Bhagwatwar et al., using different steps to carry out the same and Yeh et al. to arrive at size limitations within that contemplated herein.

Likewise, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a volume fraction of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents in the initial mixing of the goserelin acetate-polymer poly-DL-lactide-co-glycolide of Hutchinson, in view of Chen et al., and further in view of Bhagwatwar et al. or Yeh et al., because both Hutchinson and Chen et al. advantageously

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teach routinely optimizable amounts of the solutions/solvents therein, as do the latter references, to carry out the desired results of the artisan and the selection of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents in the initial mixing of the goserelin acetate-polymer poly-DL-lactide-co-glycolide, would have merely obvious depending on the results sought, absence evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960.

The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 9/29/2008

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654